

What is claimed is

1. A pharmaceutical composition for sustained release comprising as active ingredient pitavastatin or a pharmaceutically acceptable salt thereof, said composition comprising a core consisting of an inner phase (internal) and an outer phase (external) wherein the outer phase does not comprise a matrix former and wherein the core is first coated with a non functional film coat and then with an enteric coat.
2. A composition according to claim 1 wherein the amount of pitavastatin or pharmaceutically acceptable salt thereof is about 1-50 weight % of the core composition.
3. A composition according to claim 1-2 wherein the amount of pitavastatin or pharmaceutically acceptable salt thereof is about 5-50 weight % of the core composition.
4. A composition according to anyone of claims 1-3 wherein the amount of pitavastatin or pharmaceutically acceptable salt thereof is about 1-32mg.
5. A composition according to anyone of claims 1 to 4, wherein the inner phase comprises a matrix former.
6. A composition according to claim 5, wherein the matrix former comprises one or more types of matrix former component having different viscosities.
7. A composition according to claim 4 or 6, wherein the matrix former is selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, hydrophilic polymers such as hydroxypropylcellulose, hydroxymethylcellulose, and hydroxypropylmethylcellulose or the like.
8. A composition according to claim 7, wherein the matrix former is hydroxypropylmethylcellulose (HPMC).
9. A composition according to claim 8 wherein the amount of HPMC as a matrix former is about 1-60 weight % (based on the total core components).

10. A composition according to claim 9, wherein the matrix former of the inner phase has a viscosity of about 1 to about 100.000 cps.
11. A composition according to claim 9, wherein the matrix former of the inner phase has a viscosity of about 1 to about 500 cps.
12. A composition according to anyone of claims 1-11, wherein said composition comprises a stabilizer .
13. A composition according to claim 12, wherein the stabilizer is magnesium aluminometasilicate (neusilin).
14. A composition according to claim 13, wherein the amount of the stabilizer is about 1-15 weight % (based on the total core components).
15. A composition according to claims 1 to 14, wherein the non-functional coat consists in Hydroxypropylmethylcellulose ,Polyethyleneglycol, titanium dioxide and talc.
16. A composition according to claims 1 to 15, wherein the amount of non functional film coat is used at about 4 mg of film coat pro cm².
17. A composition according to claims 1 to 16, wherein the enteric coat consists in Eudragit L30D (methacrylic copolymer), talc and polyethyleneglycol.
18. A composition according to anyone of claims 1 to 17, wherein the enteric coat is used at 4 to 6 mg polymer pro cm².
19. A method of treatment of hyperlipidemia, hypercholesterolemia and atherosclerosis, as well as other diseases or conditions in which HMG-CoA reductase is implicated comprising administering to a patient in need thereof a therapeutically effective amount of a composition according to any one of claims 1 to 18.

20. Use of the composition according to any one of claims 1 to 19 in the manufacture of a medicament for use in the treatment or prevention of a cardiovascular disease, e.g., hypercholesterolemia, hyperproteinemia and /or atherosclerosis.